UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No.1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory Docket: 06-CV-11337-PBS
United States of America, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	Hon. Patti B. Saris

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION IN LIMINE TO EXCLUDE CERTAIN TESTIMONY OF DR. LAUREN J. STIROH

Defendant Dey Laboratories may call Dr. Lauren J. Stiroh, an economist, as an expert witness at trial.[1] At least five of her opinions, however, should be excluded. First, Dey seeks to offer improper expert testimony on "industry practice," a topic that is irrelevant to any issue in the case and not a valid defense. Second, Dr. Stiroh's opinion on the percentage of Dey's sales made at or near wholesale acquisition cost (WAC) is irrelevant in a Medicare-only trial and unreliable because it is based on incomplete data. Third, her opinions that Dey had no reason to believe that Medicare[2] was "deceived" by its pricing practices are neither relevant nor grounded in an area of Dr. Stiroh's expertise. Fourth, Dr. Stiroh's opinion that there were "alternative

[1] Dr. Stiroh has submitted a Report dated March 6, 2009 ("Stiroh Rep."), a rebuttal report dated May 7, 2009 ("Stiroh Rebuttal"), and a Declaration in Support of Dey's Motion for Partial Summary Judgment dated June 26, 2009 ("Stiroh Dec."). These materials are attached as Exhibits A, B and C.

[2] Dr. Stiroh opines similarly with respect to deception involving the Medicaid program. In its Sur-reply in Opposition to United States' Motion to Exclude Certain Opinions of W. David Bradford, PhD., Dkt. 772-1, at 9, Dey suggests that "the Court need not reach Dr. Bradford's Medicaid opinions at this time" given the Court's bifurcation order. As expert testimony relating to the Medicaid program would be both irrelevant and confusing, the United States agrees that the Court similarly should not address Dr. Stiroh's Medicaid opinions at this time, provided Dey agrees not to proffer them at trial.

reimbursement bases" available to Medicare is irrelevant because Dey's conduct must be evaluated against the law in existence during the relevant time period. Finally, Dr. Stiroh's opinion that overpayments by the Medicare program for Dey's drugs cannot be quantified because Congress and CMS would have changed the law if Dey had reported accurate AWPs is utter speculation and inadmissible in a False Claims Act (FCA) case.

ARGUMENT

A. Dr. Stiroh's Industry Practice Testimony Must be Excluded As Unreliable, Outside Her Area of Expertise, and Irrelevant

Dr. Stiroh opines that there was an "industry practice" among generic drug manufacturers to set and maintain reported AWPs at 10 to 20 percent off the corresponding brand AWP and that Dey's conduct in doing so was consistent with competitive behavior in the industry. Stiroh Rep., p. 14-16; May 12-13, 2009 Deposition of Lauren Stiroh ("Stiroh Dep."), 47:3 - 47:19.[3] Neither Dr. Stiroh's expertise nor her analysis, however, provide a reliable basis upon which to render an expert opinion as to whether there was an industry standard for setting generic AWPs.

During her deposition, Dr. Stiroh conceded that her "understanding" came almost exclusively from deposition testimony in connection with the litigation against Dey, largely from Dey's own witnesses. Stiroh Dep., 47:20 - 48:2. She had no specific understanding of such a general industry practice prior to being retained in this case, *id.*, 48:3 - 49:1, and does not know whether other drug companies always followed this practice. *Id.*, 60:17 - 61:11. Dr. Stiroh's conclusion here is directly at odds with the conclusion reached by Dey's other expert, Dr. W. David Bradford, who actually compared the AWPs set by the various manufacturers of generic

[3] Excerpts from Dr. Stiroh's deposition are attached as Exhibit D.

ipratropium bromide, and observed that manufacturers entered the market with several different AWPs. Dr. Bradford concluded that there is no "single dominant strategy" by which generic manufacturers set AWP. Bradford report, 37-38.

Testimony does not become admissible "expert" testimony if it merely parrots the self-serving statements of a defendant's own employees. *Lang v. Kohl's Food Stores, Inc.*, 217 F.3d 919, 924 (7th Cir. 2000) (excluding expert whose report "did little more than parrot" plaintiffs' beliefs). Moreover, the testimony relied on by Dr. Stiroh is conflicting and ambiguous. For example, Dr. Stiroh relied on testimony from Dey's Director of Marketing (Robert Mozak) in support of her claim that Dey set its AWPs at 10% below the corresponding brand AWP on advice from First Data Bank (FDB). Stiroh Rep., 16 and n.71. She seemingly ignores, however, testimony from another Dey employee (Helen Selenati) that, at Mr. Mozak's request, Ms. Selenati called FDB "to ask [ ] what is the *maximum* price that Dey Labs can list their AWP at and still be considered a generic product." August 15, 2002 Selenati Dep., at 47:4 – 47:22 (emphasis added).[4] In addition, other testimony cited (but seemingly ignored) by Dr. Stiroh makes clear that FDB did *not* have a "10% percent rule," and that the only industry perception of which FDB was aware was that generic drugs needed to be priced *at least* 10% less than AWP. Stiroh Rep., 16 n.70. Since Dr. Stiroh's opinion that Dey's pricing practices comported with an industry standard is not supported by any systematic evaluation of how generic companies set their AWPs, it should be excluded pursuant to Fed. R. Evid. 403 and 702.

Leaving aside the reliability of Dr. Stiroh's conclusion, her testimony regarding industry practice is irrelevant because industry practice is not a defense under federal law. *See, e.g.*,

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[4] Excerpts from Ms. Selenati's deposition are attached as Exhibit E.

Vermilye & Co. v. Adams Express Co., 88 U.S. 138, 146 (1874) ("If . . . [parties] have been in the habit of disregarding that law, this does not relieve them from the consequences nor establish a different law."); *SEC v. U.S. Funding Corp.*, 2006 WL 995499, at *9 (D. N.J. 2006) (striking affirmative defense that defendant acted consistent with established industry practices because such "standards and customs" do not "trump our nation's federal securities laws"). The plain language of the FCA confirms the irrelevancy of any professed belief by Dey that its conduct comported with an "industry standard":

> (1) the terms "knowing" and "knowingly" --
>
> > (A) mean that a person, with respect to information--
> > (i) has actual knowledge of the information;
> > (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> > (iii) acts in reckless disregard of the truth or falsity of the information; and
> > (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1). Dr. Stiroh's opinion that Dey's price-reporting practices comported with an industry standard is immaterial to the key issue before the jury – did Dey knowingly report false prices? *See Barragan v. Tyson Foods, Inc.*, 2008 WL 1776439, *5-6 (N.D. Iowa 2008) (excluding expert testimony on industry practice in an Family Medical Leave Act (FMLA) case; "the question here is not what the industry practice or standards are, but whether the defendants violated the plaintiff's rights under the FMLA.").

Conceivably, Dey may argue that industry practice is relevant to its "government knowledge" defense. But neither Dey nor Dr. Stiroh has offered any evidence that government policy-making officials were aware of an industry practice to report generic AWPs at ten percent below the brand AWP regardless of actual market prices. There is no evidence Dey informed the

government of this standard, and no hint of government awareness, let alone approval, of any such practice in any HHS OIG or other government reports, or in the testimony of any current or former CMS official.

B. Dr. Stiroh's Opinion about the Ostensible "Accuracy" of Dey's Reported WACs Should Be Excluded As Irrelevant in a Medicare-only Trial and Unreliable Since She Omits Over Half the Relevant Data

Dr. Stiroh opines that Dey's WACs are "economically meaningful reflections of transaction prices." Stiroh Rep., 16-17. This opinion should be excluded as irrelevant in a Medicare-only trial since Medicare has never reimbursed based on WACs. Even if such testimony were relevant, the Court should nonetheless exclude Dr. Stiroh's opinion as unreliable because she disregards over half of Dey's actual sales in order to reach her conclusion.[5]

In a Medicare-only trial, testimony about WAC is irrelevant since it is undisputed that the Medicare program has never reimbursed for albuterol or ipratropium bromide (or any other drug) on the basis of any manufacturer's reported WACs. The government's Medicare case focuses on Dey's reported AWPs, not its WACs. Furthermore, Dey reported its own AWPs and did not rely on any formulaic mark-up of its WACs by the pricing compendia. Thus, testimony about the purported accuracy of Dey's WACs is irrelevant to the questions the jury must decide in a Medicare-only trial.

Even if Dr. Stiroh's testimony on this point were determined to be relevant, her conclusions are unreliable because they depend upon excluding so many of Dey's actual sales and contradict prior holdings of this Court, as well as Dey's own practice. Exhibit 6 to Dr.

[5] The United States understands that Dey may not offer this testimony in the Medicare-only trial, in which case the Court need not address this issue.

Stiroh's expert report purports to show that, "after price adjustments," more than 70 percent of Dey's sales are within 5 percent of its reported WAC. Stiroh Rep., 17. At her deposition, however, Dr. Stiroh acknowledged that the calculations reflected in Exhibit 6 exclude "shipments where the wholesaler acted only as a distributor" and the sale was made at a contract price negotiated by Dey and the end-customer. Stiroh Dep. II:480:2-12; Decl, ¶ 11. Sales made pursuant to contracts, however, account for well over half of Dey's total sales of the drugs at issue, as is evident from a comparison of Exhibits 5 and 6 to Dr. Stiroh's report. Exhibit 5, which reflects "Non-Adjusted" sales to wholesalers shows $1.393 billion in sales; Exhibit 6, which reflects Dr. Stiroh's "Adjusted" sales (i.e., those excluding contract sales subject to chargebacks) shows sales of only $505 million. *See* Stiroh Dep. II; 485:15-486:1 (acknowledging Ex. 6 includes approximately one-third of the sales included in Ex. 5). Because the contract price was almost always lower than the WAC, Dey paid a "chargeback" equal to the difference between the WAC and the contract price to the wholesalers.[6] *See* Declaration of Simon D. Platt in Support of the United States' Motion for Partial Summary Judgment ("Platt Dec."), at ¶ 10. By excluding *all* contract sales (and the often very large chargebacks associated with them) from her calculations, Dr. Stiroh presents an incomplete and misleading picture of the relationship between Dey's WACs and its transaction prices.[7]

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[6] Dey's indirect transaction data shows approximately $1.3 billion in sales for the complaint products. Reductions from gross sales consisting of chargebacks amounted to approximately $441 million (or 34% of the total). Platt Dec. ¶14. The Platt Dec. is attached as Exhibit F.

[7] To the extent Dr. Stiroh is suggesting that contract sales do not constitute sales to wholesalers, she directly contradicts the position Dey took in its summary judgment papers. *See* Concise Statement of Undisputed Material Facts in Support of Dey's Motion for Partial Summary Judgment, ¶ 52 ("In an indirect sale with a contract, Dey negotiates a contract price with an indirect customer that will *ultimately purchase Dey's* product *from a wholesaler*") (emphasis supplied).

Dr. Stiroh's decision to exclude contract sales involving chargebacks from her calculations is also inconsistent with prior holdings of this Court as well as with Dey's own practice. This Court has construed WAC as a net price including discounts and chargebacks. *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 141-44 (D. Mass. 2008) (WACs must reflect pre-sale, rebates, chargebacks, and other discounts). In determining whether manufacturers' reported prices were false, the Court has considered *all* sales, including those made pursuant to contracts. *See, e.g.*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 105 (D. Mass. 2007) ("If more than 50 percent of *all* sales were made at or about the list price, the list price will not be deemed fictitious") (emphasis supplied).[8] In the *New York Counties* litigation, for example, the Court applied the list price test in determining whether GlaxoSmithKline's (GSK) WACs were false. The plaintiffs, the Court, and GSK considered contract sales subject to chargebacks in determining the percentage of sales sold at or near the reported WAC. *See in re Pharm. Indus. Average Wholesale Price Litig.*, 672 F. Supp. 2d 211, 215-16 (D. Mass. 2009).[9]

Tellingly, Dey itself did not distinguish between chargeback and non-chargeback sales when calculating its average sales prices. On the contrary, internal company documents indicate that Dey calculated "net sales" figures by adjusting invoice prices to account for rebates,

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[8] The Court took this same approach in its recent summary judgment opinion in the *New York Counties* litigation. *See City of New York v. Abbott Labs.* (*In re Pharm. Indus. Average Wholesale Price Litig.*), 685 F. Supp. 2d 186, 202 (D. Mass. 2010) ("Plaintiffs have presented undisputed evidence that the WACs the Defendants reported were not the prices that wholesalers actually paid to acquire their drugs and that fewer than 50% of their sales were made within 5% of their reported WACs.").

[9] *See also* GlaxoSmithKline's November 24, 2008, Memorandum of Law In Support of Its Motion for Partial Summary Judgment (Dkt. # 5707), 11 (explaining that GSK's expert "calculated transaction prices by taking into account *all* discounts and rebates given to customers and *all* chargebacks credited as the result of contracts with customers).

chargebacks and other discounts. *See* Dey-BO0031281 (attached hereto as Exhibit G). Dey's Chief Financial Officer, Pamela Marrs, explained that Dey calculates an internal average sales price as "sales dollars divided by units." She explained that in making such calculations, Dey looked to its sales reports for a particular product, then subtracted "returns, chargebacks, rebates and the various other allowances on an accrual basis divided by units." *See* August 19, 2004 Marrs Dep., 217.4 - 218.1.[10] If one calculates transaction prices as Dey itself did (and includes all wholesaler transactions, including those involving chargebacks), only approximately 3.3% of Dey's sales to wholesalers over the relevant time period were within 5% of the reported WAC. Platt Decl., ¶ 23.

Dr. Stiroh's decision to exclude contract sales from her calculations thus presents a misleading picture of the extent to which Dey's WACs correlate with transaction prices. Her opinion is both irrelevant and unreliable and should be excluded.

C. Dr. Stiroh's Opinions That Dey Had No Reason To Believe Anyone Was Deceived By Dey's Pricing Conduct Are Not Relevant to Any Issue in this Litigation

Throughout her report, Dr. Stiroh offers the opinion that given "the information available in the market," there was no reason for Dey to believe that its conduct was deceptive. *See, e.g.*, Stiroh Rep., 18 ("There is no reason for Dey to have believed that anyone was deceived by its pricing practices.").[11] Testimony of this sort is irrelevant to any issue in this case, and would

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[10] Excerpts of Ms. Marrs' deposition are attached as Exhibit H.

[11] *See also* Stiroh Rep., 3, ¶ 4 ("there is no reason for any participant in th[e pharmaceutical] market to think that Medicare or Medicaid would be or was deceived by its pricing practices"), 4, ¶ 8 ("The plaintiffs' experts do not present any evidence that Dey believed that Medicare or Medicaid was deceived by its conduct"), 35 (plaintiffs "do not present any evidence that Dey believed, or rationally could have been expected, that Medicare or Medicaid was deceived by its conduct").

only confuse the jury as to the appropriate standard for evaluating Dey's conduct.

Under the FCA, the United States need not prove that Dey had reason to believe it deceived anyone. 31 U.S.C. § 3729(b)(1)(B) (no proof of specific intent to defraud is required). On the contrary, the relevant inquiry is whether Dey acted with deliberate indifference or reckless disregard of the truth or falsity of its prices. *See Hindo v. Univ. of Health Servs./The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) ("[W]hat constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or simply false. The requisite intent is the knowing presentation of what is known to be false."); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420 (9th Cir. 1991) (same). In the New York Counties case, this Court rejected the argument that plaintiffs needed to establish that CMS or New York Medicaid was deceived to prove liability under New York's False Claims Act,[12] holding that "[d]eception of government officials . . . is not an element of Section 145-b. The plain language of the statute makes clear that liability attaches upon the attempt to obtain payment." *City of New York,* 2010 WL 582039, at * 10. *See also, Jerman v. Carlisle,* 130 S.Ct. 1605 (2010) (recognizing that "ignorance of the law will not excuse any person, either civilly or criminally," and holding that an act may be "intentional" under the Fair Debt Collection Practices Act "even if the actor lacked knowledge that her conduct violated the law.").

If whether or not the government was deceived is not relevant to establish the offense, then opinions as to whether or not Dey had reason to *think* its conduct would deceive the government are even less germane. The potential for confusion is apparent from the facts Dr.

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[12] The Court expressly recognized the similarities between the New York False Claims Act and the Federal False Claims Act. 2010 WL 582039, at * 8.

Stiroh cites in support of her opinion; namely, what she describes as the "abundant public information" about the "nature of AWPs as benchmark prices." *See* Stiroh Rep., 18-23. Permitting Dr. Stiroh to opine that the mere existence of such information – irrespective whether Dey's price-setting officials were even aware of it at the time – establishes that Dey's conduct was not "deceptive," deflects attention from the proper analysis of the FCA's "knowledge" element: whether Dey knew that its reported prices were false. As explained more fully in the United States' Motion in Limine to Preclude Evidence of Government Knowledge As Irrelvant To Falsity, Scienter, Causation Or Damages Under the FCA, these "expert" opinions invite the jury to decide the case based on irrelevant issues such as whether Dey's conduct deceived government agencies and officials. Expert testimony on this point would be unhelpful and confusing to the jury, and should be excluded.

D. Dr. Stiroh's Description of the "Alternative Reimbursement" Bases Available to Medicare Is Irrelevant and Invites the Jury to Measure Dey's Conduct Against Something Other Than the Existing Law

Dr. Stiroh opines that there were "alternative reimbursement bases" available to Medicare, including Dey's WACs, DOJ's "revised AWP prices," IMS data, and the pricing information contained in Myers and Stauffer reports. Stiroh Rep., 30-34. According to Dr. Stiroh, Medicare's continued use of AWPs rather than such "alternative" prices demonstrates that Medicare was not "misled by the pharmaceutical companies." *Id.*, 30. This testimony should be excluded as irrelevant and confusing.

Dey's conduct must be measured against the reimbursement system actually in place during the relevant time period. From 1992 through 2003, Medicare reimbursement was tied to AWP by regulation and then federal statute. *See generally In re Pharm. Indus. Average*

Wholesale Price Litig., 582 F.3d 156, 164-67 (1st Cir. 2009). Expert testimony about the "alternative prices" Congress *might* have used to determine Medicare reimbursement had it decided to scrap the AWP-based system is irrelevant to any element or defense under the FCA. The fact that Congress "could have," but did not (until after the relevant time period), base Medicare reimbursement on prices other than AWPs is not relevant to whether the AWPs Dey actually reported were false. Likewise, the existence of alternative reimbursement bases is not relevant to whether Dey acted knowingly in reporting the prices that it did, or to whether Dey's reported prices in fact caused false claims to be presented.

Dr. Stiroh's testimony on this point appears calculated to suggest that Medicare's continued use of AWPs, rather than some other reimbursement basis, reflects a deliberate choice to pay for drugs at prices well in excess of their acquisition costs and at levels determined solely by pharmaceutical manufacturers. Such an inference is entirely speculative and is well outside any expertise Dr. Stiroh possesses. It also flatly contradicts the First Circuit's finding that Congress held an "unwavering commitment" to the "policy that Medicare reimbursement should be reasonable and reflective of acquisition costs." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 170. It will be the jury's role to find facts, not to divine the meaning of statutes and legislative history. Expert testimony describing the different reimbursement bases available to Congress – and suggesting that Congress's failure to scrap the AWP-based system reflects an affirmative decision to pay inflated prices – is not helpful to any issue properly before the jury, particularly where, as here, the Court has already interpreted the relevant statutes and legislative history.

E. Dr. Stiroh's Speculation That Congress and CMS Would Have Changed Medicare Reimbursement for Pharmaceuticals Based on Dey's Reporting of Accurate Prices Is Not Admissible Testimony

Strangely, Dr. Stiroh criticizes Dr. Duggan for using the law and regulations in place during the relevant time period to estimate the government's overpayment based on Dey's false price reporting. Dr. Stiroh contends that Dr. Duggan failed to consider the "implications" of Dey's reporting different prices; specifically, she attacks plaintiffs for failing to develop "a cogent and complete theory of how CMS might have changed its reimbursement formulas, including its dispensing fees" if Dey had reported accurate AWPs. Stiroh Rep., 34. Dr. Stiroh contends that failure to evaluate how Congress would have reacted to accurate prices from Dey renders Dr. Duggan's calculations "incomplete and unreliable." *Id*. Dr. Stiroh's testimony on this topic should be excluded because it is wholly speculative and has no relevance to liability or damages under the False Claims Act.

Dr. Stiroh's "critique" turns the law of causation and damages under the FCA on its head. She states that plaintiffs' damages methodology "fails" because it "assumes, without basis or analysis" that if Dey had reported lower AWPs, the federal government would have continued to follow existing law and use the payment methodology in place at the time. Stiroh Rep., 43. In Dr. Stiroh's view, damages are calculated under the FCA not by measuring the impact of Dey's AWPs on existing payment formulas as set forth in regulation and statute, but by imagining how Congress or CMS might have changed payment formulas in response to Dey's reporting lower AWPs, such as by increasing dispensing fees. Given the whorled progress of the health care reform legislation eventually passed by Congress in 2010, it is hard to imagine a more speculative exercise.

Under the FCA, the measure of damages is commonly calculated as the difference between the amount the government paid out because of the false statements and the amount that it would have paid had the claims been truthful. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1966); *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988). Consistent with this approach, Dr. Duggan has calculated the amounts actually paid by the Medicare program for albuterol and ipratropium bromide, and then determined the amounts that would have been paid if Dey had reported truthful prices. There is nothing in FCA case law that requires Dr. Duggan to evaluate whether a defendant's truthful statements would have resulted in a wholesale change to Medicare program regulations.

Even if evidence of such possible effects is admissible in an FCA case, it is the defendant's burden to present competent, nonspeculative evidence of such indirect effects and to properly quantify the impacts. *See Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164, 182-183 (4th Cir. 2010) (affirming entry of summary judgment against defendant insurance companies, and rejecting as too speculative as a matter of law defense argument that damages should be offset by the higher insurance premiums that plaintiffs might have paid had defendants acted lawfully);[13] s*ee also Daubert*, 509 U.S. at 590 (1993) (stating that scientific knowledge requires "more than subjective belief or unsupported speculation"); *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748,

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[13] Dey argues that *Ward* "does nothing to shed light on a court's gate-keeping function" because the decision did not involve a *Daubert* motion. Sur-reply in Opposition to United States' Motion to Exclude Certain Opinions of W. David Bradford, PhD., Dkt. 772-1, at 9. Dey elevates form over substance. As *Ward* was decided on summary judgment, the Court decided that the defense argument that damages should be offset was too speculative *as a matter of law*. 595 F.3d at 164. Here, the Court should likewise exclude Dr. Stiroh's opinion because it is too speculative and therefore fails to create a factual issue for the jury.

757 (8th Cir. 2006) ("Expert evidence is unreliable if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case.").

Dey cannot meet its burden here because Dr. Stiroh lacks sufficient foundation for speculating that Congress and/or CMS would have altered the Medicare reimbursement landscape if Dey had reported truthful prices.[14] For example, the primary basis cited by Dr. Stiroh in support of her opinion that Medicare dispensing fees would have increased is that the Medicare dispensing fee for inhalation drugs increased after Congress passed the Medicare Modernization Act (MMA). As described more fully in the Reply Memorandum of United States in Support of Motion To Exclude Certain Opinions of W. David Bradford, Ph.D (Master Doc. #7055-1, Sub. #752-1) at 10-13, this opinion is pure conjecture. There is no contemporaneous evidence that during the relevant time period Medicare intended that inflated AWPs cross-subsidize the dispensing fee for inhalation therapy – or any other – drugs. *Id*. at Exhibits 2 and 3. The final dispensing fee established after the MMA was based on factual information not in existence during the relevant time period, including studies of dispensing costs in 2003 and 2004. *See* 70 Fed. Reg. 45,764, 45,847-48 (Aug. 8, 2005) (proposed rule); 70 Fed. Reg. 70,116, 70,225-33, 70,332-34 (Nov. 21, 2005) (final rule).[15] The post-MMA dispensing fee encompassed overhead and a variety of other expenses never contemplated during the relevant time period. *Id.* Moreover, the mix of information before the agency in the post-

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[14] As indicated above, at n. 2, plaintiffs assume Dey will no longer seek to offer Dr. Stiroh's testimony regarding the Medicaid program in the upcoming Medicare-only trial. To the extent Dey does proffer such testimony, it should be excluded because it is too attenuated and collateral to the issues in a Medicare trial.

[15] The agency also considered information developed in a 2004 rulemaking that established an interim dispensing fee for calendar year 2005. 69 Fed. Reg. 47,488, 47,546-47,550 (Aug. 5, 2004) (proposed interim rule); 69 Fed. Reg. 66,236, 66,337-42, 66,425 (Nov. 15, 2004) (final interim rule).

MMA rulemaking included evidence that Medicare had previously over-paid for the nebulizer equipment used to deliver the drugs, *see* 68 Fed. Reg. 50,428, 50,441 (Aug. 20, 2003), and that the MMA significantly reduced the payment not only for the inhalation therapy drugs, but for the nebulizer DME as well. Pub. L. 108-173, § 302(c)(2), 117 Stat 2066 (Dec. 8, 2003); *see* 69 Fed. Reg. 47,488, 47,549 (Aug. 5, 2004). In short, this aptly illustrates the many moving parts that make up any significant statutory and regulatory change to the Medicare program. To contend that a similar process, yielding a similar result (an increased dispensing fee), would have resulted if Dey had reported truthful prices for the drugs at issue during the relevant time period is sheer speculation.

In addition, Dr. Stiroh's suggestion that Congress and CMS sought to pay providers above their acquisition costs distracts the jury from its proper function as the finder of fact. The proper role of the jury in this case is not to decide how policy makers and others in the Medicare program might have resolved the purported tension between controlling costs and affording access to medical care. Rather, the role of the jury is to decide, as a matter of *fact*, whether Dey's AWPs were false under existing law, whether Dey had "knowledge" that they were false, and what amount of damages were proximately caused by any falsity found. Expert testimony that Congress and CMS would have changed the law if Dey had reported truthful prices risks inviting the jury to evaluate Dey's conduct against something other than the applicable law, and encourages outright speculation.

In sum, testimony by Dr. Stiroh that Medicare's dispensing fee would have increased had Dey reported accurate AWPs is sheer conjecture. She has offered no reliable methodology for second-guessing whether Congress or CMS would have (1) increased the dispensing fee for

inhalation therapy drugs, and, if so, by how much, or (2) made any other legislative changes. Based as it is on guesswork, the testimony should be excluded under Fed. R. Evid. 403 and 702.

CONCLUSION

For the reasons stated above, the Court should grant the United States' motion and exclude testimony by Dr. Stiroh on the five topics cited by plaintiffs.

Respectfully submitted,

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CERTIFICATION

The undersigned certifies that counsel for the United States and for Dey have conferred pursuant to LR 7.1(A)(2), in a good faith attempt to resolve or narrow the issues addressed in this motion.

/s/ *James J. Fauci*
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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: June 7, 2010

/s/ *James J. Fauci*
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